

REMARKS

The office action dated July 28, 2009 has been studied in detail along with the references cited and applied by the Examiner. In response, selected claims have been amended (claims 46). The pending claims should be read in conjunction with the accompanying arguments in support of patentability. Further examination and consideration of the application as amended are respectfully requested.

THE OFFICE ACTION

Claims 46-47 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 6-21, 34-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vandervelde et al. (WO 91/07876) in view of Berger (US PN 4,574,084).

Claims 1, 3, 6-21, 34-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harwardt et al. (DE 41 37 544) in view of Berger.

REJECTIONS UNDER 35 U.S.C. §112

Claims 46-47 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant in the present amendment has amended claim 46 to particularly point out and claim the subject matter. Namely, amended claim 46 now recites ". . . applying a pharmaceutical preparation to the area to be treated; wherein said pharmaceutical preparation including comprises alkali and/or alkaline earth salts of tosylchloramide, and wherein said tosylchloramide salts . . .".

As amended, claim 46 now shows that the tosylchloramide is part of the pharmaceutical preparation.

REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 1, 3, 6-21, 34-47 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vandevelde et al. (WO 91/07876) in view of Berger (US PN 4,574,084).

Combination of Vandevelde and Berger

Contrary to the Examiner's assertion, applicant is not attacking the references individually, but rather, the Applicant is demonstrating that each reference does not show what the Examiner asserts and thus the combination of the references, in turn, cannot show what the Examiner asserts.

The Examiner states on page 4 of the most recent Office Action that Berger "discloses the general teaching that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi. Furthermore, these skin diseases can be effectively treated with biocidal compositions that are used for disinfection". The Examiner then discounts Applicant's arguments that Berger does not teach that skin diseases can be treated with any biocidal composition used for disinfection.

The Examiner then comments, in response to Applicant's arguments, that the Berger reference was "used to show the general teaching that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi. In this manner, the Berger reference was not relied on for any teaching of therapeutically active agents" (bottom of page 5 in Examiner's latest Office Action). Here the Examiner responds to Applicant's arguments regarding Berger and comments that Berger has only been used to show the general teaching that common inflammatory skin diseases are caused by bacteria, viruses, and fungi.

If the general teaching of Berger is merely to show that common inflammatory skin diseases are caused by bacteria, viruses and fungi, then the Examiner has not demonstrated a *prima facie* case of obviousness. The Examiner here argues that the Berger reference was not relied on for any teaching of therapeutically active agents.

Thus, a *prima facie* case of obviousness has not been established because the combination of Vandevelde et al. and Berger does not make obvious Applicant's claims.

But, contrary to that assertion, the Examiner has stated in multiple occurrences that Berger is relied on for showing not only that common inflammatory skin diseases are caused by bacteria, viruses, and fungi, but also that skin diseases can be effectively treated with biocidal compositions that are used for disinfection. If the latter is the argument that the Examiner is relying upon, Applicant has argued and continues to argue that this latter assertion is not accurate. Namely, Berger does not provide the general teaching that skin diseases can be treated with any biocidal composition used for disinfection. Applicant tried to demonstrate in its previous responses, including an exhibit, that biocidal compositions that are used for disinfection are not necessarily suitable for treating skin diseases. Quite the opposite is found. In particular, many biocidal compositions are possible for disinfection, but contact must be avoided with the skin, eyes, etc. The date of publication of the previously filed exhibit is not pertinent to this argument. Applicant was merely demonstrating one such example where a biocidal composition should not and cannot be used for treating skin diseases. There are many other examples that Applicant can provide. Applicant is merely trying to rebut the Examiner's assertion that Berger provides a general teaching that skin diseases can be treated with any biocidal composition.

In Applicant's previous responses, where Applicant has tried to make the aforementioned argument, the Examiner then states that Berger is merely relied upon for the general teaching that common inflammatory skin diseases are caused by bacteria, viruses, and fungi. The Examiner appears to advance differing arguments regarding the teachings found in Berger. The Examiner presents a confusing and contradictory assessment of the Berger reference and has presented a difficult circumstance for Applicant to argue what the reference does or does not show. Again, Applicant is not trying to attack the references individually, but rather is trying to assert what each reference teaches. Thus, once the teachings have been identified, the combination of these references can then be ascertained. In light of the above, Applicant contends that Berger does not provide the general teaching that common skin diseases such as psoriasis and herpes can be treated with biocidal compositions that

are used for disinfection. Therefore, one of ordinary skill would not have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition as disclosed by Vandervelde et al.

Further, as discussed above, if the general teaching in Berger is only that skin diseases are caused by bacteria, viruses, and fungi, then the *prima facie* case of obviousness has not been established, thus the combination of Berger and Vandervelde et al. does not make obvious Applicant's claims.

On the other hand, if Berger is being used to disclose the general teaching that skin diseases can be effectively treated by biocidal compositions that are used for disinfection, then Applicant has legitimately countered that assertion by demonstrating that Berger does not provide the general teaching that skin diseases can be effectively treated with any biocidal composition that is used for disinfection. The latter general teaching has not been demonstrated by Berger and is not supported by evidence in the field of disinfection. Many biocidal compositions that are used for disinfection are harmful and dangerous to any contact with the skin or eyes and are extremely detrimental to any type of skin contact or for any type of treatment for skin diseases.

Furthermore, the Examiner asserts on page 6 of the most recent Office Action that Vandervelde clearly teaches tosylchloramides, and its known derivatives, can be used for topical administration to skin broadly and hair and can be used in methods of treating skin diseases. The Examiner further states that "the mere mention that chloramine-T acts against viruses on inanimate objects provides sufficient motivation to administer a composition comprising chloramine-T as a medicament or a pharmaceutical composition for treating other skin diseases". This statement is merely a conclusory statement not supported by any evidence, nor is it supported by any references cited by the Examiner. To the contrary, any mention that a particular compound can act against a virus on an inanimate object does not alone provide sufficient motivation to administer the same composition for treating skin diseases. As discussed above, many disinfectants, used for inanimate objects, cannot and should not be used for topical treatment of skin diseases. Many disinfectants are extremely dangerous and detrimental to any type of skin contact. One can not merely assert that any disinfectant used for disinfecting inanimate objects provides sufficient motivation to

administer the same composition for treating skin diseases. That statement is not supported by the evidence in the record nor is it supported by the knowledge of one skilled in the art.

None of the cited references, either singularly or in combination, provide any teachings for addressing the problems addressed by the present application. There is no suggestion, motivation, or teaching to combine the references. There is no motivation to combine the cited references to modify their teachings to reach the above referenced claims. “The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious”. *United States v. Adams*, 383 U.S. 39, 51-52 (1966); and cited with approval in *KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-1741 (2007).

Although taught away from, if one combines the teaching of Berger with Vandevelde one may add to the tosylchloramide-T compound of Vandevelde additionally a peroxide of Berger to stabilize this compound for the purpose of disinfection. If one starts from Vandevelde, one comes to the same conclusion, i.e. to combine for disinfection purposes the chloramine-T with additional stabilizing peroxide compounds for disinfecting HIV contaminated dead bodies.

However, in each scenario one does not arrive at the method recited in claims 1, 34, and 46.

Applicant submits that there is no suggestion to combine the teachings and suggestions of Vandevelde and Berger, as advanced by the Examiner, except for using Applicant's disclosure as a template through a hindsight reconstruction of Applicant's claims.

Claims 1, 3, 6-21, and 34-47 were rejected under 35 U.S.C 103(a) as being unpatentable over Harwardt et al. in view of Berger.

The Examiner states “Harwardt et al. does not expressly disclose the employment of tosylchloramides in methods of the particular skin diseases herein”. The Examiner further asserts that “Berger teaches as discussed above”.

The arguments raised above are equally appropriate here. Again, the Examiner appears to rely on Berger for teaching that common skin diseases are caused by bacteria, viruses, and fungi, and also that Berger provides the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Applicant has countered the Examiner's assertions as discussed in detail above. The Examiner concludes that at the bottom of page 8 that "one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition comprising tosylchloramide as disclosed by Harwardt et al. because of the beneficial therapeutic effects of tosylchloramides on killing and destroying harmful microorganisms that cause such skin diseases".

The Examiner's conclusory statement is not supported by the evidence nor is it supported by the combination of Harwardt and Berger as discussed in detail above. The Examiner expressly states "Harwardt et al. does not expressly disclose the employment of tosylchloramides in methods of the particular skin diseases herein" but later states that, because of Harwardt et al., the beneficial therapeutic effects of tosylchloramides on killing and destroying harmful microorganisms that cause such skin diseases is somehow disclosed. Again, Applicant finds it difficult to counter the assertions of the Examiner as arguments and observations of the cited references are altered and described in conclusory statements rather than by supported evidence in the record.

The Examiner attempts to demonstrate that the generalization or broadening of the Berger reference is to use a particular teaching of a chlorite solution with a peroxide stabilizer used as a biocidal compound, provides the general teaching that skin diseases can be treated with any biocidal composition used for disinfection.

To the contrary, Berger does not teach that any kind of biocidal composition can be used for the treatment of skin diseases. Berger specifically states that "the agent according to the invention and particularly the sodium chlorite solution can also be used for treating skin diseases . . ." (column 8, lines 9-11).

To illustrate that there is no general teaching of a nexus between skin diseases and biocidal compositions that are used for disinfection, Applicant submitted a Technical Data Bulletin in the previous amendment.

The Examiner acknowledges that Harwardt et al. does not expressly disclose the employment of tosylchloramide in methods of the particular skin diseases herein, and since Berger does not provide the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection; one of ordinary skill in the art would not have had a reasonable expectation of success in treating skin diseases caused by herpes simplex virae as recited in Applicant's claims.

None of the cited references, either singularly or in combination, provide any teachings for addressing the problems as identified by Applicant. There is no motivation to combine any of the cited references to modify their teachings to reach the above referenced claims.

Combining the cited references would not result in Applicant's claimed invention as recited above. In effect, the combination of references stated in the office action is being assembled to address the problem Applicant is addressing by the method described by Applicant. Consequently, independent claims 1, 34 and 46, and all claims dependent therefrom, define over any fair teachings attributable to the references either taken singularly or in combination.

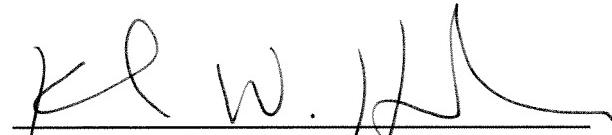
CONCLUSION

All formal and informal matters having been addressed, this application is in condition for allowance. Early notice to that effect is solicited. Applicant's attorney can be reached at the telephone number below if any further information is needed.

Respectfully submitted,

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SEPT. 10, 2009
Date



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